

Application No.: 09/836,627
Atty. Dkt. No: 6514-11-BHJ

REMARKS

Applicant respectfully requests reconsideration of the present application in view of the reasons which follow.

Claims 1-25 and 29-33 stand rejected. Claims 22 and 23 have been cancelled without prejudice. Accordingly, Claims 1-22, 24, 25 and 29-33 are pending in this Application.

Claim Rejections – 35 U.S.C. § 103

In Section 2 of the Office Action, the Examiner rejected Claims 1-25 and 29-33 under 35 U.S.C. § 103(a) as being unpatentable over EP 0754452 A2 (Hatano et al.), in view of WO 95/35100 (Watts). The Examiner stated in Section 4:

Applicant argues that none of the prior art teaches a HPMC coating consisting essentially of a single coating. In response to said argument, it is noted that Applicant's invention reads on a drug delivery composition consisting essentially of a HPMC capsule provided with a single aqueous coating, and not on a HPMC coating consisting essentially of a single coating, as argued by Applicant. The single aqueous coating claimed by Applicant does not exclude the presence of additional coatings, as in fact claim 22, which depends on claim 1 of the instant application, reads on a composition, wherein the HPMC capsule body is coated with an insoluble polymer and the cap is enteric or colonic coated. Thus, in Applicant's invention the HPMC capsule body is coated with an insoluble polymer and a single aqueous coating. Hatano et al. contemplates a single aqueous coating, as the reference teaches that the enteric polymer, which is a polymer soluble in an aqueous medium at pH higher than 5, may be used alone (Seep. 4, line 46 to p. 5, line 11).

Claim 1 recites "[a] drug delivery composition consisting essentially of a HPMC capsule capable of containing the drug, wherein the HPMC capsule is provided with a single aqueous coating such that the drug is not released from the capsule in the stomach."

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1. Independent Claim 1 is limited to exclude additional coatings that do not materially alter the basic characteristic of a single aqueous coating and is therefore allowable over the cited references.

"The transitional phrases 'comprising', 'consisting essentially of' and 'consisting of' define the scope of a claim with respect to what unrecited additional components or steps, if any, are excluded from the scope of the claim." M.P.E.P. 2111.03. "The transitional phrase 'consisting essentially of' limits the scope of a claim to the specified materials or steps 'and those that do not materially affect the basic and novel characteristic(s)' of the claimed invention. In re Herz, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original)." M.P.E.P. 2111.03.

As recited in the claims, at least one of the basic and novel characteristics of Claim 1 is a drug delivery composition consisting essentially of an "HPMC capsule...provided with a single aqueous coating." The transition phrase "consisting essentially of" limits the scope of a claim to the specified materials i.e., a single or non-layered aqueous coating that do not materially alter the basic characteristic of a single aqueous coating. The transition phrase "consisting essentially of" excludes additional coatings that materially alter the basic characteristic of a single aqueous coating. Furthermore, the claim language itself (a single aqueous coating) limits the scope of a claim to the specified materials that do not materially alter the basic characteristic of a single aqueous coating. Accordingly, Claim 1 is limited to exclude additional coatings that do not materially alter the basic characteristic of a single aqueous coating.

The Examiner asserts that the "single aqueous coating claimed by Applicant does not exclude the presence of additional coatings, as in fact claim 22, which depends on claim 1 of the instant application, reads on a composition, wherein the HPMC capsule body is coated with an insoluble polymer and the cap is enteric or colonic coated." Section 4 of the Office Action.

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Claims 22 and 23 have been cancelled without prejudice in order to expedite prosecution on the merits of the remaining claims. However, Applicants respectfully submit that claim 22 (which recited a capsule body and a cap, each provided with a single aqueous layer) is not inconsistent with Applicants' assertion that independent Claim 1 is limited to exclude additional coatings that do not materially alter the basic characteristic of a single aqueous coating.

Applicants respectfully submit that independent Claim 1 is limited to exclude additional coatings that do not materially alter the basic characteristic of a single aqueous coating (i.e., a single or non-layered coating such that the drug is not released from the capsule in the stomach).

2. The combination of features recited in independent Claim 1 is not disclosed, taught or suggested by the cited references, alone or in any proper combination.

The Examiner stated "Hatano et al. contemplates a single aqueous coating, as the reference teaches that the enteric polymer, which is a polymer soluble in an aqueous medium at pH higher than 5, may be used alone (See p. 4, line 46 to p. 5, line 11)."

Hatano et al. does not contemplate a single aqueous coating as recited in independent Claim 1. Hatano et al. teaches that each capsule is coated with two separate layers (an enteric coating and a polymer film soluble at low pH). The section referred to by the Examiner (p. 4, line 46 to p. 5, line 11) teaches that different examples or types of an enteric polymer (such as a cellulose derivative, an acrylic copolymer, a maleic copolymer, a polyvinyl derivative, shellac, etc.) (p.4, lines 50-51) "may be used alone or in the combination of one or more kinds thereof" in the enteric coating (p. 5, lines 13-14). Hatano et al. still teaches that two separate layers (an enteric coating and a polymer film soluble at low pH) are provided. "In accordance with the present

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invention, there is provided a pharmaceutical preparation in the form of a coated capsule which can release contents of a capsule at a lower part of the digestive tract comprising (a) a hard capsule containing at least an acidic substance, (b) a polymer film soluble at low pH which is formed on a surface of said hard capsule, and (c) an enteric coating film which is formed on a surface of said polymer film soluble at low pH." EP 0754452, ¶ 0016. The section referred to by the Examiner only teaches that the enteric layer may be a single material or a mixture of different enteric polymers. Hatano et al. does not teach an "HPMC capsule...provided with a single aqueous coating such that the drug is not released from the capsule in the stomach."

The combination of features recited in independent Claim 1 is not disclosed, taught or suggested by the cited references, alone or in any proper combination. Accordingly, Applicants respectfully request withdrawal of the rejection of independent Claim 1 (and corresponding dependent Claims 2-21, 24, 25 and 29-33).

* * *

Applicants submit that the rejection of Claims 1-21, 24, 25 and 29-33 has been overcome. Accordingly, withdrawal of the rejection of Claims 1-21, 24, 25 and 29-33 is respectfully requested. Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

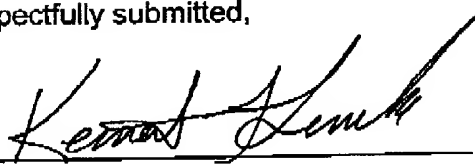
The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 23-0455. If any extensions of time are needed for timely acceptance of papers submitted herewith, applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 23-0455.

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Respectfully submitted,

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